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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/381,286	12/07/99	GROLL	M P564-9039

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EXAMINER

LUNDGREN, J

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/381,286	Applicant(s) GROLL ET AL.	
	Examiner Jeffrey Lundgren	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV (claims 15-20) in Paper No. 8 (received on February 26, 2001) is acknowledged. The traversal is on the ground(s) that the subject matter is so "intertwined" that restriction is improper.

This is not found persuasive because restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to any question regarding the serious burden of search, the literature search between different groups, particularly relevant in this art, is not co-extensive and is highly important in evaluating the burden of search.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to because of the following informalities: Applicants refer to Table 1 (for example, see page 13, line 20), yet there are no tables disclosed in the instant specification. Applicants can overcome this objection by deleting all references in the specification to Table 1.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants disclose an experimental procedure wherein 14 genes cloned from yeast which code for components of the 20S proteasome are studied using x-ray crystallography (see Example 2 on page 13), however, the crystallographic data is not present in the Application as filed. Applicants refer to certain crystallographic studies pertaining to proteasomes that have been reported in the prior art (pages 1-5). Applicants also disclose certain features with respect to their results from the crystallographic studies, such as, a description of the data by reference to contacts (paragraph bridging pages 18 and 19), the discussion with respect to the β -trans- β interactions (paragraph bridging pages 19 and 20), the identification of certain residues that are important to the structural integrity near the N-terminal threonine position (page 20), and so forth throughout the remainder of pages 21-30.

However, the limitations drawn to data and/or data pertaining to the crystal structure, does not meet the written description provision of 35 USC 112, first paragraph. Applicants have not reasonably defined the essential elements of their data/crystal structures, such that the skilled artisan would be able to distinguish the invention being claimed from other crystallographic data structures. The invention not only fails to meet the written description requirement as a result of Applicants failure to provide the data describing the crystallographic structure in a Table format (or another acceptable format), but Applicants reliance on the crystal structures of the prior art, in combination with the features as described on pages 16-30, does not describe the essential features which would describe the data/crystal structures which Applicants are claiming from other data/crystal structures. Also, the claimed method encompasses methods of use of the data/crystal structure of corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), which are not disclosed. The

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specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The court found in Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, that written description requires more than a mere statement that the claimed nucleic acid sequence is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. Similarly, Applicants data/crystal structure of the proteasome do not meet the written description requirement. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-20 are indefinite for failing to recite any positive active steps. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986).

Claims 16-20 are indefinite for reciting the term "crystal structure", because the skilled artisan would not reasonably be able to determine the metes and bounds of this limitation.

Claims 16 and 20 recite the limitation "the crystal structure". There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the region". There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the proteasome pockets". There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the subunits". There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the crystal structural data". There is insufficient antecedent basis for this limitation in the claim.

Claim 20 is indefinite for reciting the phrase "which is complementary to", because the skilled artisan could not reasonably determine the metes and bounds of this limitation.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. The invention of claims 15-19 is directed to non-statutory subject matter, as Applicants invention is drawn to "uses".

Conclusion

9. No claims are allowable.

10. Any inquiries concerning the *merits* of this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren, whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4426.

Any inquiries of a *general* nature relating to this application should be directed to Ms. Pauline Farrier, Patent Analyst for Art Unit 1631, whose telephone number is (703) 305-3550.

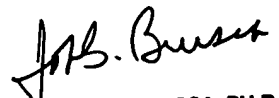
Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax

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number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).



Jeffrey S. Lundgren, Ph.D.



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER